



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.]

Issued: April 19, 2002

Posted: April 26, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-4

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a durable medical equipment company's proposal to place its portable oxygen systems on-site at certain local hospitals, clinics, and physician offices for distribution to certain departing patients (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement

would not constitute grounds for the Office of Inspector General (“OIG”) to impose administrative sanctions on [Company A] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act).

This opinion may not be relied on by any persons other than [Company A], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Company A] (the “Requestor”), a durable medical equipment (“DME”) company, provides and delivers DME, including home oxygen systems, to patients within its service area. Under the Proposed Arrangement, the Requestor will place an inventory of its portable oxygen equipment on-site at certain local hospitals, clinics, and physician offices (collectively, the “Distributors”) for distribution to those patients who are bound for home, whose physicians have ordered portable oxygen equipment for home use, and who have elected to obtain the equipment from the Requestor. Once distributed, the Distributor will provide to the Requestor notice of the distribution, including the patient’s name and insurance information, and the Requestor will bill the patient and/or his or her third party payor.

The Requestor plans to offer the Proposed Arrangement to clinics and physician offices within its service area that refer patients to the Requestor for home oxygen systems and to all hospitals within its service area. The Proposed Arrangement between the Requestor and each Distributor will be set forth in writing and signed by both parties. The Requestor has certified that it will not pay the Distributors for use of the “consignment closets” and that, accordingly, the Distributors will receive no remuneration from the Requestor in connection with the Proposed Arrangement. The Requestor has further certified that, to protect patient freedom of choice, the Requestor will provide to each Distributor a list of local DME suppliers and encourage each Distributor to provide the list to its patients.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible

"kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Our office closely scrutinizes arrangements between sellers and potential referral sources to determine whether a seller offers or provides any remuneration that is intended, in whole or in part, to induce or reward referrals. In the instant case, no remuneration flows from the Requestor to its potential referral sources, the Distributors, in connection with the Proposed Arrangement. Therefore, we conclude that the Proposed Arrangement does not implicate the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute and, therefore, the Proposed Arrangement would not constitute grounds for the OIG to impose administrative sanctions on [Company A] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Company A], which is the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestor with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be

Page 5 - OIG Advisory Opinion No. 02-4

rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General